UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

NATIONAL INFUSION CENTER ASSOCIATION et al.,	§	No. 1:23-CV-707
Plaintiffs,	§	
vs.	§	
ROBERT R. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, et al.,	§	
Defendants.	§	

ORDER ON CROSS-MOTIONS FOR SUMMARY JUDGMENT

Before the Court are (1) Plaintiffs Pharmaceutical Research and Manufacturers of America ("PhRMA"), Global Colon Cancer Association ("GCCA"), and National Infusion Center Association's ("NICA"), (collectively "Plaintiffs") Motion for Summary Judgment, filed on January 10, 2025 (Dkt. # 60), and (2) Defendants Robert F. Kennedy, Jr.,[1] in his official capacity as Secretary of the United States Department of Health and Human Services, the United States

[1] Pursuant to Federal Rule of Civil Procedure 25(d), Robert F. Kennedy, Jr., Secretary of Health and Human Services, is automatically substituted as a defendant in his official capacity for his predecessor, Xavier Becerra. Dr. Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, is likewise automatically substituted as a defendant in his official capacity for his predecessor, Chiquita Brooks-Lasure.

Department of Health and Human Services, Dr. Mehmet Oz, in his official capacity as Administrator of the Centers for Medicare and Medicaid Services, and the Centers for Medicare and Medicaid Services' (collectively, the "Government" or "Defendants") Response and Cross-Motion for Summary Judgment, filed on April 21, 2025. (Dkt. # 70.)

On May 27, 2025, Plaintiffs filed their reply in support of their motion for summary judgment. (Dkt. # 85.) On July 3, 2025, Defendants filed their reply in support of their cross-motion for summary judgment. (Dkt. # 88.) Also before the Court are Amicus Briefs filed by (1) Public Citizen, Doctors for America, Protect Our Care, and Families USA; (2) nationally recognized experts in healthcare, healthcare finance, and Medicare; and (3) economists and health policy scholars who focus their work on healthcare markets and pharmaceutical drug pricing. (Dkts. # 73-1, 79-1, 80-1.)

The Court finds this matter suitable for disposition without a hearing. After careful consideration of the memoranda filed in support of and against the motions, the Court (1) **DENIES** Plaintiffs' Motion for Summary Judgment, and (2) **GRANTS** Defendant's Cross-Motion for Summary Judgment.

BACKGROUND

Plaintiffs in this action, Pharmaceutical Research and Manufacturers of America ("PhRMA"), Global Colon Cancer Association ("GCCA"), and

National Infusion Center Association ("NICA"), challenge the constitutionality of the Drug Pricing Program created by the Inflation Reduction Act of 2022, Pub. L. No. 117-169, (the "IRA" or the "Act"). PhRMA is a non-profit corporation that serves as the "pharmaceutical industry's principal policy advocate." (Dkt. # 1 at 10.) PhRMA's members include pharmaceutical and biotechnology companies. (Id.) GCCA is a non-profit corporation that represents "millions of colon cancer patients worldwide[.]" (Dkt. # 1 at 9.) NICA is a non-profit corporation that represents non-hospital, community-based infusion providers. (Dkt. # 1 at 8.)

Plaintiffs name four defendants: the United States Department of Health and Human Services ("HHS"), the Centers for Medicare and Medicaid Services ("CMS"), Robert F. Kennedy, Jr. (in his official capacity as Secretary of HHS), and Dr. Mehmet Oz (in his official capacity as Administrator of CMS).

I. Medicare

Enacted in 1965, Medicare is a federal program that pays for covered healthcare items and services, including prescription drugs, for qualified beneficiaries. See generally 42 U.S.C. § 1395 et seq. The Secretary ("Secretary") for the HHS operates Medicare through the CMS. 42 U.S.C. § 1395u. Medicare offers two prescription drug programs—Medicare Part B and Part D. Medicare Part B covers medically necessary and preventative healthcare services, including prescription drugs. 42 U.S.C. §§ 1395k(a)(1), 1395x(s)(2)(A). Under Part B,

CMS will reimburse prescription drug providers, based on the "average sales price" of the drug. See 42 U.S.C. § 1395w-3a. Medicare Part D is a voluntary outpatient drug benefit, provided by privately-operated plans. 42 U.S.C. § 1395w-102. Drug prices in Part D are market-based and administered by private plan sponsors, which negotiate prices with manufacturers. The government covers a portion of the cost of covered drugs through Medicare Part D.

Prior to the IRA, Congress barred the Secretary from negotiating drug prices under Part D or otherwise interfering in the commercial arrangements between manufacturers and the private insurance plans that, in turn, enter into agreements with Medicare to provide benefits. See 42 U.S.C. § 1395w-111(i).

II. The Drug Price Negotiation Program

In 2022, Congress passed the IRA. Pub. L. No. 117-169 §§ 11001-11003, 136 Stat. 1818 (codified in pertinent part at 42 U.S.C. §§ 1320f–1320f-7 and 26 U.S.C. § 5000D). As part of the IRA, Congress directed the Secretary of HHS to establish a "Drug Price Negotiation Program" (the "Program"). 42 U.S.C. § 1320f(a). The Program aims to limit the cost of certain drugs under Medicare Parts B and D. 42 U.S.C. § 1320f et seq. The Secretary has delegated authority to CMS to negotiate prices for certain drugs that have resulted in high expenditures to Medicare. Id. As stated by the Fifth Circuit, the Program can be broken down into three phases: the drug selection phase, the negotiation phase, and (if necessary) the

penalty phase. See Nat'l Infusion Ctr. Ass'n v. Becerra, 116 F.4th 488, 495 (5th Cir. 2024) (NICA).

Through this Program, the HHS ranks and selects "negotiation-eligible drugs" and then negotiates with the manufacturers to determine a "maximum fair price." 42 U.S.C. § 1320f–2(a)(1); 1320f–1(b)(1)(A). CMS is instructed to identify a set of "negotiation-eligible drug[s]" from a set of "qualifying single source drugs." 42 U.S.C. § 1320f-1(d)–(e). Congress directed CMS to select up to 10 such drugs for negotiation for initial price applicability for year 2026, up to 15 drugs for initial price applicability for years 2027 and 2028, and up to 20 drugs for initial price applicability for year 2029 and for subsequent years. Id. § 1320f-1(a)–(b).

After selecting the drugs, CMS is directed to negotiate with the manufacturer of each selected drug in an effort to reach agreement on a "maximum fair price" for that drug. Id. § 1320f-3. To conduct the "negotiations," the statute directs HHS to "develop and use a consistent methodology and process … to achieve the lowest maximum fair price for each selected drug." Id. § 1320f–3(b)(1). That process includes an HHS "offer," a manufacturer "counteroffer," and an HHS "[r]esponse." Id. § 1320f–3(b)(2)(B)–(D).

Once a maximum fair price is set, manufacturers must provide the drugs at that price to individuals, pharmacies, providers, and other entities

participating in Medicare. 42 U.S.C. § 1320f–2(a)(1). Manufacturers that fail to do so may pay a per-unit penalty of ten times the difference between the price charged and the maximum fair price, transfer its interest in the drug to another entity, or withdraw from Medicare and Medicaid Programs. 42 U.S.C. § 1320f–6(b); CMS, Medicare Drug Price Negotiation Program: Revised Guidance 129–131 (June 30, 2023), https://perma.cc/K6QB-C3MM ("Revised Guidance"); 26 U.S.C. § 5000D(c)(1).

The IRA further provides that "[t]here shall be no administrative or judicial review" of "[t]he selection of drugs," "the determination of negotiation-eligible drugs," "the determination of qualifying single source drugs," and "[t]he determination of a maximum fair price." 42 U.S.C. § 1320f–7(2)–(3).

III. The Excise Tax

Manufacturers that do not sign the Manufacturer Agreement or agree to the maximum fair price may be subject to an excise tax on sales of Selected Drugs for each day of the "noncompliance periods." 26 U.S.C. § 5000D(a)-(b). The Department of the Treasury, of which the IRS is a part, is charged with enforcing section 5000D and interpreting its provisions. See § 5000D(h) ("The Secretary shall prescribe such regulations and other guidance . . . ."); see also 26 U.S.C. § 7701(a)(11)(B) ("When used in this title, . . . [unless otherwise stated], [t]he term 'Secretary' means the Secretary of the Treasury or his delegate."). The

applicable percentage starts at 65% and then increases 10% for each quarter of noncompliance until it reaches 95%. Id.

IV. Procedural Background

On June 21, 2023, Plaintiffs brought a facial constitutional challenge to the portions of the IRA that create the Program, asserting that these provisions violate (1) the nondelegation doctrine, (2) the Excessive Fines Clause of the Eighth Amendment, and (3) the Due Process Clause of the Fifth Amendment. (Dkt. # 1.)

On February 12, 2024, this Court granted Defendants' motion to dismiss. (Dkt. # 53.) The Court held that the Medicare Act's channeling provision deprived it of subject-matter jurisdiction to address Plaintiff NICA's claims, and that venue was thus improper. (See id. at 12–13.) On September 20, 2024, the Fifth Circuit vacated and remanded for further proceedings, holding that Plaintiff NICA had adequately alleged Article III standing, and that channeling under the Medicare Act was not required. See NICA, 116 F.4th at 509.

On January 10, 2025, Plaintiffs filed their motion for summary judgment. (Dkt. # 60.) On April 21, 2025, the Government filed its cross-motion for summary judgment. (Dkt. # 70.) The motions are ripe for consideration.

LEGAL STANDARD

"Summary judgment is appropriate only if 'there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.'"

Vann v. City of Southaven, 884 F.3d 307, 309 (5th Cir. 2018) (citations omitted); see also Fed. R. Civ. P. 56(a). Claims turning entirely on the constitutional validity or invalidity of a statute are particularly conducive to disposition by summary judgment as they involve purely legal questions. See Ctr. for Individual Freedom v. Carmouche, 449 F.3d 655, 662 (5th Cir. 2006).

DISCUSSION

Plaintiffs raise several constitutional challenges to the Program, arguing that (1) the IRA violates separation of powers based on the nondelegation doctrine; (2) the IRA violates the Eighth Amendment's Excessive Fines Clause; and (3) the IRA violates the Fifth Amendment's Due Process Clause. The Court addresses each argument in turn.

I. Nondelegation Doctrine

Plaintiffs argue that the IRA violates the separation of powers by giving HHS unconstrained discretion to set prices for drugs without clear statutory guidance or meaningful judicial review. (Dkt. # 60 at 24–26.) The Government argues that the IRA includes sufficient direction regarding eligible drugs, negotiation timelines, and factors for pricing decisions to be a constitutional delegation to HHS. (Dkt. # 70 at 26–27.)

Under Article I of the U.S. Constitution, "[a]ll legislative Powers herein granted shall be vested in a Congress of the United States." U.S. Const. art.

I, § 1. The nondelegation doctrine bars Congress from transferring its legislative power to another branch of Government. Gundy v. United States, 588 U.S. 128, 132 (2019) (plurality). At the same time, the Supreme Court has recognized that Congress may "seek[ ] assistance" from its coordinate branches to secure the "effect intended by its acts of legislation." Fed. Commc'ns Comm'n v. Consumers' Rsch., 145 S. Ct. 2482, 2491 (2025) (quoting J. W. Hampton, Jr., & Co. v. United States, 276 U.S. 394, 406 (1928)). Thus, Congress does not violate the Constitution merely because it legislates in broad terms, leaving a certain degree of discretion to executive or judicial actors. Touby v. United States, 500 U.S. 160, 165 (1991).

Delegation of authority to an agency can violate the nondelegation doctrine if: (1) Congress failed to provide an intelligible principle by which an agency can exercise its authority; or (2) power granted to an agency is vast beyond measure, akin to ability to regulate entire economy on basis of no more precise standard than stimulating economy by assuring fair competition. Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 472 (2001); Airlines for Am. v. Dep't of Transportation, 127 F.4th 563 (5th Cir. 2025). The Supreme Court has consistently explained that the standards to satisfy an intelligible principle to guide an agency's exercise of authority "are not demanding." Gundy, 588 U.S. at 146 (2019). It is well-accepted that it is "constitutionally sufficient if Congress clearly delineates

the general policy, the public agency which is to apply it, and the boundaries of this delegated authority." Am. Power & Light Co. v. SEC, 329 U.S. 90, 105 (1946).

A. History of Nondelegation Doctrine

The Supreme Court has only twice in its history struck down federal laws under the nondelegation doctrine. First, in Panama Ref. Co. v. Ryan, 293 U.S. 388, (1935) the Court addressed Section 9(c) of National Industrial Recovery Act ("NIRA"), which gave the President the authority to prohibit the transportation of petroleum in interstate commerce if it had been produced in violation of state laws or quotas. Id. at 405. The law further allowed the President to impose punishments for violating any of his orders. Id. The Court held the law was an unconstitutional delegation of legislative power because it gave the President an "unlimited authority" to determine policy and to lay down the prohibition, or not to lay it down, as he saw fit. Id. at 414–15. The Court reasoned that Section 9(c) failed to specify when or under what conditions the President could prohibit the transportation of excess petroleum, provided no standards to guide the President's decision, and did not require any factual findings before acting. Id. at 415. In effect, Congress offered no policy direction regarding the regulation of excess petroleum production. Id.

Second, in A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495 (1935), the Court addressed Section 3 of the NIRA, which authorized the

President to approve "codes of fair competition" developed by industry groups, with the force of law. Id. at 521–22. The Court found that this delegation lacked clear standards or limits to guide the President's discretion, effectively granting him unchecked legislative authority. Id. at 538–39. The case established that while Congress may delegate rulemaking authority, it must lay down standards to guide the exercise of that authority. Id. at 541. In this case, the statute provided no such standards or restrictions, allowing the President to legislate with virtually unfettered discretion. Id. at 542.

On the other hand, the Supreme Court has affirmed Congressional authorizations to (1) regulate in the "public interest," Nat'l Broad. Co. v. United States, 319 U.S. 190, 225–26 (1943) (broadcast licensing); (2) set "just and reasonable" rates, FPC v. Hope Natural Gas Co., 320 U.S. 591, 600 (1944) (natural gas); and (3) set air-quality standards that are "requisite to protect the public health," Am. Trucking, 531 U.S. at 472–76, because the discretion given in those matters, among others, was not unbridled.

Recently, the Supreme Court rejected a party's request to create a special nondelegation rule for revenue-raising legislation in Consumers' Research. There, the Court addressed whether the universal service contribution framework under the Communications Act violates the nondelegation doctrine. 145 S. Ct. at 2491. Specifically, the case involved a challenge to the Federal Communications

Commission's ("FCC") authority to collect and distribute funds via the Universal Service Fund ("USF") and its sub-delegation of administrative duties to a private entity, the Universal Service Administrative Company ("USAC"). Id.

Using the intelligible principal standard, the Court concluded Congress provided adequate policy direction and statutory limits in Section 254 of the Communications Act to the FCC. Id. at 2501-03. This included clear identification of beneficiaries (e.g., low-income consumers, rural areas, schools, and libraries), guidance on what types of services may be subsidized, and a requirement that contributions be "sufficient" to support universal service. Id. at 2503–04. Because Congress provided these objectives, the Court held there were meaningful constraints on the FCC's discretion. Id. at 2507, 2511.

The Court further rejected the Fifth Circuit's "combination" theory used to conclude that the USF was an unconstitutional delegation of Congress's authority. Id. at 2510. Here, Plaintiffs attempt to argue that "features of the Drug Pricing Program *combine* to violate the Constitution's separation of powers." (Dkt. # 60 at 27) (citing Consumers' Rsch. v. Fed. Commc'ns Comm'n, 109 F.4th 743, 788 (5th Cir. 2024)). And again, in its reply, Plaintiffs maintain "[t]he IRA's nondelegation problem is that it *combines* these features, giving HHS legislative discretion without any meaningful checks." (Dkt. # 85 at 18.) Because the

Supreme Court declined to adopt a "combination" analysis in a delegation challenge, this Court declines to do so here.

B. Intelligible Principle

The Government contends the Program provided sufficient constraints to CMS's discretion. (Dkt. # 70 at 25–26.) This Court agrees. First, Congress defined the critical terms. See 42 U.S.C. § 1320f(b), (c). Second, Congress established detailed criteria for the selection of negotiation-eligible drugs and selected drugs. See id. § 1320f-1. Third, Congress established multiple mathematical formulae for calculating ceiling prices. See id. § 1320f-3(c). Fourth, Congress specified the procedures for negotiation, including the specific timing deadlines that vary across different price applicability years. See id. § 1320f-3. Finally, Congress established detailed parameters for agreements with participating manufacturers. See id. § 1320f-2.

Plaintiffs argue that "[w]hile the statute directs HHS to 'consider' certain 'factors,' it provides *no* guidance on how to weigh those factors and sets *no* concrete limits on the agency's discretion—other than a minimum discounted 'ceiling' price and a general instruction to 'achieve the *lowest* maximum fair price.'" (Dkt. # 60 at 26) (emphasis in original). Thus, according to Plaintiffs, Congress delegated "untrammeled discretion to wield command-and-control authority over vast swaths of the economy." (Id.)

The Court finds the IRA provides sufficient guidance to the HHS and CMS. In administering the Program, Congress directed CMS to "aim[] to achieve the lowest maximum fair price for each selected drug" for which it is able to persuade manufacturers to sign an agreement. 42 U.S.C. § 1320f-3(b)(1). This suffices as an intelligible principle accompanying the delegation. Moreover, Congress provided detailed criteria CMS was required to consider in "determining the offers and counteroffers" during the negotiation, up to the congressionally specified ceiling price, using data "submitted by the manufacturer" including:

> (A) Research and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped research and development costs.
> (B) Current unit costs of production and distribution of the drug.
> (C) Prior Federal financial support for novel therapeutic discovery and development with respect to the drug.
> (D) Data on pending and approved patent applications, exclusivities recognized by the Food and Drug Administration, and applications and approvals under [the Food Drug and Cosmetic Act].
> (E) Market data and revenue and sales volume data for the drug in the United States.

Id. § 1320f-3(e)(1). The above criteria more than suffice to provide guidance to CMS to enforce the Program. And to the extent that Plaintiffs argue the Program grants CMS discretion on *how to weigh* the criteria, that does not run afoul of the delegation doctrine because Congress is indeed allowed to legislate in broad terms and to leave discretion to the agency. See Touby, 500 U.S. at 165.

Plaintiffs argue the Program's inclusion of a price ceiling, but not a floor, is also problematic. (Dkt. # 60 at 16–17.) The Government responds the nondelegation doctrine requires only an intelligible principle, and the provision of a ceiling price coupled with detailed criteria for the agency's offers and counter offers easily meets that standard. (Dkt. # 70 at 28.) In Consumers Research, the Court determined that the word "sufficient" sets a floor and a ceiling alike. Consumers' Research, 145 S. Ct. at 2491. An amount of money is "sufficient" for a purpose if it is "[a]dequate" or "necessary" to achieve that purpose. Id. Similarly, here, the use of a "maximum fair price" is sufficient to guide HHS and CMS to set the prices of the drugs selected for the Program. 42 U.S.C. § 1320f-3(c).

The Court concludes Congress defined both "the general policy" that the agency must pursue and "the boundaries of th[e] delegated authority." Am. Power & Light, 329 U.S. at 105. Therefore, the Court finds the IRA and its Drug Pricing Program is a constitutional delegation to the HHS and CMS.

This Court is not alone in concluding that the IRA does not violate the nondelegation doctrine. In Novo Nordisk Inc. v. Becerra, the district court found "that Congress's delegation in the IRA easily passes constitutional muster because it articulates an 'intelligible principle' to guide CMS during the negotiation process." No. CV 23-20814, 2024 WL 3594413, at *8 (D.N.J. July 31, 2024). The

court reasoned the IRA conveys a specific, delineated task to CMS, and it explains the scope and parameters of the delegation throughout the statute. Id. Thus, the court concluded that while the statute sets forth a broad delegation to CMS to negotiate maximum fair prices for selected drugs, it also narrowly defines relevant terms, sets forth the timelines for the various applicability periods, and provides CMS with guidance during the price negotiation phase. Id.

C. Judicial Review

Plaintiffs take issue with Section 1320f-7 of the IRA, which provides that there shall be no administrative or judicial review of any of CMS's election of drugs under section 1320f-1(b), the determination of negotiation-eligible drugs under section 1320f-1(d), the determination of qualifying single source drugs under section 1320f-1(e), the determination of a maximum fair price, or the determination of renegotiation-eligible drugs. 42 U.S.C. § 1320f-7.

Plaintiffs maintain that whether "judicial review is possible" of a Congressional act is a "key factor" in the nondelegation inquiry. (Dkt. # 60 at 23.) Plaintiffs argue that because "the IRA purportedly *eliminates* judicial review of critical administrative decisions," the HHS is granted with unreviewable authority, which violates the delegation doctrine. (Id. at 24.) Further, in their reply, Plaintiffs clarify they "are not arguing that the preclusion of review *alone* renders the IRA unconstitutional." (Dkt. # 85 at 16.)

Plaintiffs rely on Touby v. United States to support the proposition that the purpose of the nondelegation doctrine is to permit a court to ascertain whether the will of Congress has been obeyed. (Dkt. # 60 at 23.) In Touby, the Supreme Court rejected the Petitioners' argument that the statute was unconstitutional because it barred judicial review. 500 U.S. at 169. The Court reasoned that relevant statute *did* allow for judicial review, so the Court did not have to (and did not) say whether the nondelegation doctrine required that result. Id. at 168–69. Further, the Court concluded that under those circumstances, the nondelegation doctrine does not require, in addition, an opportunity for pre-enforcement review of administrative determinations. Id. at 169.

The Government argues that limitations on judicial review have no connection to the operative question under the nondelegation doctrine, which is whether Congress provided an intelligible principle to guide agency discretion. (Dkt. # 70 at 28.) Moreover, the Government contends it is routine in the Medicare context to limit judicial review. (Id.) Indeed, Congress has enacted dozens of similar provisions to the one at issue here. See, e.g., 42 U.S.C. §§ 1395 et seq. (repeatedly using the phrase "no administrative or judicial review").

Other courts have similarly held that judicial review preclusion is not necessary to satisfy the intelligible principle standard. United States v. Bozarov, 974 F.2d 1037, 1045 (9th Cir. 1992) ("[T]he EAA's preclusion of judicial review

does not violate the nondelegation doctrine."); Cnty. of El Paso v. Chertoff, No. EP-08-CA-196-FM, 2008 WL 4372693, at *5 (W.D. Tex. Aug. 29, 2008) ("[T]he Supreme Court does not require judicial review to satisfy the intelligible principle standard.").

The Novo Nordisk district court, discussed above, also found that preclusion of judicial review is not related to the nondelegation doctrine because it focuses on "the power Congress has delegated to the Executive Branch, on the front end—not whether the exercise of that power is subject to otherwise-unrelated constraints, on the back end." 2024 WL 3594413, at *8. There, the plaintiffs did not cite to any authority that stands for the proposition that Congress's decision to preclude judicial review triggers a violation of the nondelegation doctrine issue. Id. This Court finds Plaintiffs face similar difficulty here.

Accordingly, for the reasons provided, the Court concludes that the IRA does not violate the nondelegation doctrine and it does not violate separation of powers. The Government is entitled to summary judgment on Plaintiffs' claim.

II. Eight Amendment Excessive Fines Clause

Plaintiffs also challenge the IRA's excise tax provisions under the Excessive Fines Clause of the Eighth Amendment. (Dkt. # 60 at 27.) Specifically, Plaintiffs contend that the tax is punitive as it targets constitutionally protected

behavior of refusing a compelled "negotiation" and is grossly disproportionate to any governmental harm. (Id. at 27–31.)

Under the Eighth Amendment, "[e]xcessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted." U.S. Const., amend. VIII; Timbs v. Indiana, 586 U.S. 146, 151 (2019). At issue here is the Excessive Fines Clause, which "limits the government's power to extract payments, whether in cash or in kind, 'as punishment for some offense.'" Austin v. United States, 509 U.S. 602, 609–610 (1993) (emphasis deleted); United States v. Bajakajian, 524 U.S. 321, 328 (1998).

The Government contends that the Court lacks jurisdiction over Plaintiffs' Excessive Fines Clause because the claim cannot be redressed in this suit against the HHS and CMS. (Dkt. # 70 at 33.) Further, the Government argues Plaintiffs' excise-tax claim is barred by the Anti-Injunction Act ("AIA") and the tax exception to the Declaratory Judgment Act ("DJA"). (Id. at 34.)

A. Standing

The Government first argues Plaintiffs lack Article III standing to press their constitutional challenge to the excise tax because Plaintiffs' claim cannot be redressed against HHS and CMS. (Dkt. # 70 at 32.) HHS does not administer the IRA's tax provisions, which are codified in the Internal Revenue Code. See 26 U.S.C. § 5000D. Instead, the Department of the Treasury, of which

the IRS is a part, is charged with enforcing section 5000D and interpreting its provisions. (Dkt. # 70 at 33.)

A plaintiff establishes standing by sufficiently alleging: "(1) an 'injury in fact' that is 'concrete and particularized' and 'actual or imminent'; (2) is fairly traceable to the defendant's actions; and (3) is likely to be redressed by a favorable decision." Barilla v. City of Houston, 13 F.4th 427, 431 (5th Cir. 2021) (citing Lujan v. Defs. of Wildlife, 504 U.S. 555, 560–61 (1992)).

According to the Government, the Court cannot enter judgment against the Treasury and the IRS because they are "not parties to the suit" and they would not be "obliged to honor an incidental legal determination the suit produced." (Dkt. # 70 at 33.) Therefore, the Government contends Plaintiffs lack standing for their challenge to the excise tax because neither remedy Plaintiffs seek would provide them with any redress. (Id.)

Plaintiffs respond that the named defendants have a clear (statutorily mandated) role in enforcing the excise tax provisions, so there is no question that Plaintiffs' claim is redressable in this suit. (Dkt. # 85 at 10.) Plaintiffs aver that an injunction against the HHS would protect Plaintiffs from the harm the excise tax inflicts, because the HHS fills an integral role in its enforcement. (Id. at 26.)

Because the Court finds the Anti-Injunction Act ("AIA") applies to this matter, as discussed below, it need not address whether Plaintiffs have Article III standing to bring their tax-challenge.

B. Anti-Injunction Act

The AIA provides that "no suit for the purpose of restraining the assessment or collection of any tax shall be maintained in any court by any person." 26 U.S.C. § 7421(a); Franklin v. United States, 49 F.4th 429, 434 (5th Cir. 2022). Courts have zealously guarded this rule, recognizing the importance of the government's ability "to assess and collect taxes alleged to be due without judicial intervention" so that "the United States is [assured] of prompt collection of its lawful revenue." Id. (citing Enochs v. Williams Packing & Navigation Co., 370 U.S. 1, 7, (1962).

The Fifth Circuit has held the AIA provision to be a jurisdictional condition that "divests courts of subject-matter jurisdiction" over such cases. Matter of Westmoreland Coal Co., 968 F.3d 526, 533 (5th Cir. 2020). As a result, "a person can typically challenge a federal tax only after he pays it, by suing for a refund." CIC Services, LLC v. IRS, 593 U.S. 209, 211 (2021); Flynn v. U.S. ex rel. Eggers, 786 F.2d 586, 588 (3d Cir. 1986) (explaining that the AIA requires tax challenges "be determined in a suit for refund"). The Supreme Court has further

explained that the AIA "draws no distinction between regulatory and revenue-raising tax rules." CIC Services, LLC, 593 U.S. at 225.

To determine whether the AIA applies, courts ask (1) whether the exaction at issue is a "tax," and (2) whether the purpose of the claim is to "restrain[] the assessment or collection" of that tax. 26 U.S.C. § 7421(a). The Government argues the AIA applies and bars Plaintiffs' excise tax claim because (1) the section 5000D excise tax is a "tax" for AIA purposes as Congress "label[ed]" it as such, and (2) the purpose of Plaintiffs' excise-tax claim is to "restrain[] the assessment or collection" of the section 5000D tax. (Dkt. # 70 at 35–36.)

Plaintiffs maintain the AIA does not apply because the excise "tax" does not even seek to collect revenue. Plaintiffs cite to estimates from the Congressional Budget Office (CBO) and the Joint Commission on Taxation, which state the excise tax "would raise no revenue because no manufacturer could afford to pay it." (Dkt. # 60 at 18) (citing Joint Comm'n on Tax'n, Estimated Budget Effects of the Revenue Provisions of Title XIII – Committee on Ways and Means, of H.R. 5376, The "Build Back Better Act" at 8 (Nov. 19, 2021)).

The Government responds that a "so-called regulatory tax—'a tax designed mainly to influence private conduct, rather than to raise revenue'—does not have a special pass from the AIA." (Dkt. # 70 at 35–36) (citing Novartis, 2024

WL 4524357, at *3). Moreover, the Government contends Plaintiffs' excise-tax claim squarely targets the assessment of the tax. (Id. at 36.) This Court agrees and finds that Section 5000D is a tax for AIA purposes.

Even if the AIA applies, Plaintiffs argue the excise tax satisfies two exceptions created by the Supreme Court. (Dkt. # 60 at 31.) The first exception applies when Congress has not provided "an alternative legal way to challenge the validity of a tax." South Carolina v. Regan, 465 U.S. 367, 373 (1984). The second exception provides that a suit for injunctive relief against the collection of taxes may proceed if the government cannot possibly prevail in its claim for the taxes and the taxpayer will be irreparably harmed by the collection of the taxes. Williams Packing, 370 U. S. at 7.

i. *South Carolina* Exception

Plaintiffs argue that because "no manufacturer could afford to pay" the excise tax, (citing NICA, 116 F.4th at 495), the typical "alternative avenue for federal court jurisdiction"—"a postpayment refund suit"—is not available here. (Dkt. # 60 at 31.) Plaintiffs contend to hold otherwise would perversely allow the government to preclude an excessive fines challenge by intentionally making the fine too excessive to pay beforehand. (Id.)

The Government argues Plaintiffs cannot meet this "very narrow" exception because it applies only when Congress has not "provided an alternative

avenue for an aggrieved party to litigate its claims," necessitating the party harmed by the tax to find a third party to assert the legal issues. (Dkt. # 70 at 38) (citing South Carolina, 465 U.S. at 381). The Government's position is that a refund suit is in fact an adequate remedy. (Id. at 36.)

According to the Government, the excise tax is imposed on each "sale" of a designated drug, 26 U.S.C. § 5000D(a), and is thus a "divisible tax," meaning "one that represents the aggregate of taxes due on multiple transactions (e.g., sales of items subject to excise taxes)." (Id. at 37.) That means a manufacturer challenging a divisible tax need only pay "the excise tax on a single transaction [to] satisfy" the general rule that it must fully pay the tax before suing to seek a refund. (Id.) And according to the Government, while a refund suit is pending, the IRS typically does not collect the balance of any divisible tax that would otherwise be due, except when unusual circumstances warrant. See IRS Policy Statement 5-16, IRM § 1.2.1.6.4(6) ("When a refund suit is pending on a divisible assessment, the Service will exercise forbearance with respect to collection provided that the interests of the government are adequately protected and the revenue is not in jeopardy.").

Plaintiffs claim manufacturers cannot stake their survival on the IRS favorably exercising discretion. (Dkt. # 60 at 32.) "And even if the IRS were to forbear, additional drug sales would still generate billions in excise tax liability,

which manufacturers cannot feasibly incur." (Id.) The Court finds this argument unpersuasive because the tax liability is based on the aggregate of separate taxes due on multiple transactions.

The Court concludes that Plaintiffs can bring a refund suit after incurring the tax on a single transaction. See Rocovich v. United States, 933 F.2d 991, 995 (Fed. Cir. 1991). The IRA's excise tax is imposed on each "sale . . . of any designated drug," 26 U.S.C. § 5000D, and it is therefore divisible. Thus, the Government has sufficiently established that manufacturers need not pay the entire tax upfront while they wait for courts to adjudicate their Eighth Amendment claim.

ii. *Williams Packing* Exception

Under this exception, Plaintiffs must show "[1] irreparable injury," and "[2] certainty of success on the merits", which is a "stringent" test. Bob Jones Univ. v. Simon, 416 U.S. 725, 737 (1974). "Unless both conditions are met, a suit for preventive injunctive relief must be dismissed." Alexander v. Ams. United, 416 U.S. 752, 758 (1974). "Certainty of success" means "it is clear" that "under no circumstances could the Government ultimately prevail." Bob Jones Univ., 416 U.S. at 737.

Turning to the irreparable injury requirement, Plaintiffs argue that manufacturers attempting to pay the excise tax before suing would cause irreparable economic injury, in some cases "liability of 100 percent of the

manufacturer's total net revenues." (Dkt. # 60 at 32.) The Government argues that because a refund suit is an adequate remedy, Plaintiffs cannot establish that they or their members will suffer irreparable harm absent preemptive injunctive relief. (Dkt. # 70 at 36.) If there is any harm, that harm "is minimal": a manufacturer would "need to pay the excise tax on only one transaction in order to bring the refund suit." (Id. at 37.)

For the same reasons discussed above, the Court finds Plaintiffs have not established they will suffer irreparable injury because Plaintiffs can bring a refund suit after incurring the tax on a single transaction.

Even if Plaintiff could show irreparable harm, it must be "clear that under no circumstances could the government ultimately prevail" on its defense of the merits. Williams Packing, 370 U.S. at 7. Plaintiffs' view is that the sole purpose of the IRA's statutory scheme is to punish noncompliant manufacturers; thus, the Excessive Fines Clause applies. (Id. at 28–29.) Under the Eighth Amendment's excessive fines standard, Plaintiffs argue that the excise tax is punitive and grossly disproportionate, so under no circumstance can the Government prevail. (Id. at 32.) The Government argues that "[t]he excise tax is not a 'fine' covered by the Eighth Amendment because it is not 'punishment for some offense.'" (Dkt. # 70 at 39) (quoting Bajakajian, 524 U.S. at 327).

The Court finds Plaintiffs have not established that there are "no circumstances" in which the Government could ultimately prevail because their Eighth Amendment claim is novel and far from certainty. As the Government correctly points out, Plaintiffs have not identified any case in which a court has applied the Excessive Fines Clause to a monetary amount that was not connected to criminal conduct or a criminal proceeding. (Dkt. # 70 at 40.) And the Supreme Court has indeed recognized that "taxes that seek to influence conduct are nothing new." Nat'l Fed'n of Indep. Bus. v. Sebelius, 567 U.S. 519, 567 (2012) (NFIB).

Because Plaintiffs have not met their burden, the Williams Packing exception to the AIA does not apply here. Therefore, the Court concludes that the AIA divests it of jurisdiction to consider Plaintiffs' pre-enforcement Eighth Amendment challenge to the excise tax.

III. Fifth Amendment Due Process Clause

Finally, Plaintiffs argue that the IRA deprives them of protected property interests—such as property rights, participation in Medicare, pricing autonomy, and patent rights—without procedural safeguards or meaningful judicial review. (Dkt. # 60 at 33.) Defendants respond that none of Plaintiffs' theories establish a deprivation of any constitutionally protected interest. (Dkt. # 70 at 46.)

The Due Process Clause of the Fifth Amendment provides that "No person shall . . . be deprived of life, liberty, or property, without due process of law

. . . ." U.S. Const., amend. V. To raise a procedural due process claim, plaintiffs must "(1) identify a liberty or property interest, (2) show that the state has deprived [it] of that interest, and (3) show that the deprivation was [e]ffected without due process." Baldwin v. Daniels, 250 F.3d 943, 946 (5th Cir. 2001); Am. Mfrs. Mut. Ins. Co. v. Sullivan, 526 U.S. 40, 59 (1999).

A. Property Interest

The existence of a protected property interest is a threshold issue when reviewing a procedural due process claim: "If there is no protected property interest, there is no process due." Spuler v. Pickar, 958 F.2d 103, 106 (5th Cir. 1992). "To have a property interest in a benefit, a person clearly must have more than an abstract need or desire" and "more than a unilateral expectation of it. He must, instead, have a legitimate claim of entitlement to it." Board of Regents of State Colleges v. Roth, 408 U.S. 564, 577 (1972). The Court must first conclude that Plaintiffs have been deprived of a protected interest before it can consider whether the IRA and the Program comport with due process.

To begin, Plaintiffs point the Court to the Fifth Circuit's conclusion on appeal that "NICA has alleged sufficient facts to satisfy the Mathews[2] test."

[2] The Mathews test provides in pertinent part: "First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the Government's interest, including the function involved and the fiscal and administrative burdens

NICA, 116 F.4th at 503. On appeal, the Fifth Circuit explained "[t]he Drug Pricing Program substantially impacts [providers'] revenue and ability to stay in business." Id. Plaintiffs contend this conclusion is dispositive because "the Fifth Circuit necessarily determined that Plaintiffs have a property interest that triggers the protections of the Due Process Clause." (Dkt. # 60 at 33.)

However, the Court notes that while Plaintiffs were required to demonstrate a concrete interest tethered to the alleged deprivation of due process to establish their standing, that inquiry is not identical to the question of whether they have stated a claim for a procedural due process violation, which requires a protected liberty or property interest. The threshold for the former is lower. For example, the Fifth Circuit has explained that, even if a plaintiff's stake does not rise to the level of a liberty or property interest, "it may be 'enough to satisfy the injury-in-fact requirement of standing.'" Pierre v. Vasquez, No. 20-51032, 2022 WL 68970, at *2 (5th Cir. Jan. 6, 2022) (citing Sims v. Young, 556 F.2d 732, 734 (5th Cir. 1977)); Lujan, 504 U.S. at 572 n.7 (finding that the plaintiff had standing to assert a procedural right "even though he cannot establish with any certainty" the desired outcome of the procedure).

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that the additional or substitute procedural requirement would entail." Mathews v. Eldridge, 424 U.S. 319, 335 (1976). The Court need only address this test if Plaintiffs are able to sufficiently identify cognizable private, property interests.

Thus, the question before the Fifth Circuit on appeal was not whether Plaintiffs had alleged a protected property interest, but instead "whether the plaintiff's alleged injury is 'concrete,' 'particularized,' and 'actual or imminent.'" Pierre, 2022 WL 68970 at *2. Here, the Fifth Circuit concluded NICA has standing in this matter because it identified a concrete interest, not because it had identified a property interest. Indeed, the Government maintains "[t]here is no basis to read to the Fifth Circuit's opinion as having prejudged the merits of this case, in an opinion about jurisdiction." (Dkt. # 70 at 46 n.20.)

Therefore, the Court finds the Fifth Circuit did not "necessarily determine" Plaintiffs have a property interest in this case. Accordingly, the Court turns to the parties' arguments on the merits as to whether Plaintiffs have identified a protected property interest in their procedural Due Process claim. The Court will not reach the second question because, as explained below, Plaintiffs cannot demonstrate any deprivation of a protected interest

i. Providers' Interest

Plaintiffs contend drug providers have a protected interest in being reimbursed on a non-arbitrary basis at a lawful rate and in their investment in "building facilities and processes for administering Medicare-reimbursed drugs." (Dkt. # 60 at 34.) The Government responds providers have no protected interest in being reimbursed at their preferred levels. (Dkt. # 70 at 52.)

The Supreme Court has held that a "generalized right to be secure in one's business interests" is *not* a protectible property interest under the Due Process Clause of the Fourteenth Amendment. College Sav. Bank v. Florida Prepaid Postsecondary Educ. Expense Bd., 527 U.S. 666, 672 (1999). The Government contends that in Rock River Health Care, the Seventh Circuit also explicitly rejected the theory on which Plaintiffs rely here: that the providers were "entitled to a *particular* reimbursement rate" or "to whatever rate [the providers] believe is appropriate," divorced from any actual legal prescription. (Dkt. # 70 at 53) (citing Rock River Health Care, LLC v. Eagleson, 14 F.4th 768, 774 (7th Cir. 2021) (providers entitled only to the amount due under the legally proscribed "method of calculating the appropriate reimbursement rate," which formula was "strictly prescribed by the state law and administrative code").

Indeed, in Judge Ramirez's concurrence and dissent, she explains that under 42 U.S.C. § 1395w-3a(b)(1)(B), providers will be reimbursed "106 percent of the maximum fair price" of drugs administered incident to their services. NICA, 116 F.4th at 513 (Ramirez, J., concurring). NICA's members therefore have a statutorily created interest in being reimbursed what section 1395w-3a(b)(1)(B) allows—106 percent of the maximum fair price of a drug administered incident to their services—but NICA does not identify another law that entitles its members to more. Judge Ramirez concluded that because the text of the statute does not entitle

NICA's members to a profit from Part B reimbursements, it has not identified a concrete interest of which its members are deprived. Id. Specifically, NICA's members do not have a concrete interest in profiting from Medicare reimbursements. And as discussed above, the threshold to establish a concrete interest is lower and different than establishing a property interest for Fifth Amendment purposes.

Accordingly, the Court finds Plaintiffs have not established providers, such as those represented by NICA, have any constitutionally protected interest in being reimbursed at their *preferred* levels in the Medicare program.

Next, the Government argues that even assuming Plaintiffs have a protected interest in their facilities and their administration processes, Plaintiffs make no attempt to explain how the Program effects a deprivation of such interests as the Program does not seize providers' facilities or otherwise interfere with their "processes for administering Medicare-reimbursed drugs." (Dkt. # 70 at 53.) The Court agrees that the Program does not interfere with Plaintiffs' physical property interests. Accordingly, the Court finds Plaintiffs have not established that drug providers have any property interests that are affected by the IRA.

ii. Manufacturers' Interests

Plaintiffs next argue the IRA deprives manufacturers of their protected interests (1) in their patents and (2) of the "right to offer access to their products at

prices set by voluntary agreements." (Dkt. # 60 at 34–35.) Plaintiffs argue that prior to the enactment of the IRA, manufacturers invested in their patents and products in reliance on the principle that, "[u]pon grant of the patent, the only limitation on the size of the carrot should be the dictates of the marketplace." (Id. at 35) (citing King Instruments Corp. v. Perego, 65 F.3d 941, 950 (Fed. Cir. 1995). Thus, "[i]n upending that principle, the selection of a manufacturer's drug for government price controls under the IRA deprives that manufacturer of its property rights." (Id.)

The Government argues that manufacturers have no constitutional right to sell to the government at a preferred price. (Dkt. # 70 at 47.) According to the Government, courts have repeatedly held that no one is entitled to sell the Government drugs at prices the Government won't agree to pay. (Id.) (quoting Coyne-Delany Co. v. Cap. Dev. Bd., 616 F.2d 341, 342 (7th Cir. 1980) (per curiam)). Here, on negotiating the price that Medicare will pay for drugs, the Government is acting as a market participant. (Id. at 48.) The Program sets the terms of the Government's offer to pay for certain drugs, and manufacturers have no right to force the Government to pay for its drugs on different terms. (Id.)

In AstraZeneca Pharm. LP v. Becerra, the manufacturer made a similar "patent rights" argument to establish a property interest. 137 F.4th 116 (3d Cir. 2025). As the Third Circuit recognized, patent rights exist to permit greater

profits during a product's exclusivity period to incentivize innovation. Id. at 125; see Eldred v. Ashcroft, 537 U.S. 186, 215–16 (2003). However, "the federal patent laws do not create any affirmative right to make, use, or sell anything." Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362, 1372 (Fed. Cir. 2007) (citation omitted). "And where federal patent laws do not confer a right to sell at all, they do not confer a right to sell at a particular price." AstraZeneca Pharm, 137 F.4th at 125.

The AstraZeneca district court also explained the plaintiff "could not credibly allege that the Government's refusal to purchase a drug at the price demanded by AstraZeneca constitutes patent infringement." AstraZeneca Pharm. LP v. Becerra, 719 F. Supp. 3d 377, 395 (D. Del. 2024). The district court further found that plaintiff AstraZeneca's " desire' or even 'expectation' to sell its drugs to the Government at the higher prices it once enjoyed does not create a protected property interest" and that "because AstraZeneca has no legitimate claim of entitlement to sell its drugs to the Government at any price other than what the Government is willing to pay, its due process claim fails as a matter of law." Id. at 396 (citing Town of Castle Rock, Colo. v. Gonzales, 545 U.S. 748, 756 (2005)).

The Court finds that Plaintiffs fail to establish manufacturers have a cognizable property interest in their patent rights that is affected by the IRA.

With respect to Plaintiffs' voluntary agreement argument, the Government responds that the Program "simply establishes maximum prices the Government will pay for selected drugs" that are dispensed, furnished, or administered to Medicare beneficiaries. (Dkt. # 70 at 48.) And because participation in Medicare and Medicaid is voluntary, the Government argues the Program does not enact a deprivation of any property. (Id.)

Plaintiffs argue that withdrawal from Medicare and Medicaid to avoid the IRA is not a cognizable option. (Dkt. # 60 at 37.) According to Plaintiffs, there is nothing "voluntary" about being forced to choose between acceding to the government's demands on pain of massive penalties or withdrawing from nearly half of the national market for prescription drugs. (Id.) Plaintiffs argue manufacturers have spent billions of dollars developing innovative medicines long before the IRA was enacted, so they were not "on notice" and did not assume the risk that pricing would later be decided by the Government. (Id.)

Plaintiffs rely on the Supreme Court's rejection of the "voluntariness theory" in NFIB v. Sebelius. (Dkt. # 60 at 38.) In NFIB, the Court held unconstitutional a provision of the Affordable Care Act that withdrew all Medicaid funding from states that "opt[ed] out of the Affordable Care Act's [Medicaid] expansion." 567 U.S. at 581. The Court found that "[t]he threatened loss of over 10 percent of a State's overall budget . . . is economic dragooning that leaves the

States with no real option but to acquiesce in the Medicaid expansion." Id. at 582. However, NFIB involved the anti-commandeering doctrine, which bars "federal legislation that commandeers a State's legislative or administrative apparatus for federal purposes." Id. at 577. "No similar limit on Congress' spending powers applies here, where the government is dealing with private parties instead of state agencies. The federal government is free to use its economic power as a bulk purchaser of certain goods to negotiate better deals for those goods." Boehringer Ingelheim Pharm., Inc. v. United States Dep't of Health & Human Services, No. 3:23-CV-01103 (MPS), 2024 WL 3292657, at *15 (D. Conn. July 3, 2024). The Government also contends "[a]ny downward 'pressure' on prices that Congress may exert through the terms of its procurement offers is analogous to the leverage of any well-funded market participant, which is of no constitutional import." (Dkt. # 70 at 51.) The Court agrees and finds Plaintiffs' reliance on NFIB unavailing in their Due Process challenge.

Plaintiffs also argue that manufacturers could not exit Medicare and Medicaid immediately even if they wanted to, which further establishes the Program is not voluntary. (Dkt. # 60 at 39.) The Medicare Part D statute delays a manufacturer's ability to terminate its relevant agreements with HHS for 11 to 23 months. See 42 U.S.C. §§ 1395w-114a(b)(4)(B)(ii), 1395w-114c(b)(4)(B)(ii), 1395w–153(a)(1). The Government submits that CMS guidance confirms that a

manufacturer may withdraw through an accelerated path. (Dkt. # 70 at 20, 50 n.22.)

CMS guidance states that, upon notice from the manufacturer that it does not wish to participate in the Program and that it requests termination, CMS will "facilitate an expeditious termination of" the manufacturer's Medicare agreements before the manufacturer would incur liability for any excise tax, so long as the manufacturer notifies CMS of its desire to withdraw at least 30 days in advance of when that tax would otherwise begin to accrue. (See Revised Guidance at 33–34) (CMS "will automatically grant such termination requests upon receipt"). Existing statutes also permit CMS to "provide for termination of" Medicare agreements after 30 days for "knowing and willful violation of the requirements of the agreement or other good cause shown." 42 U.S.C. §§ 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i).

Based on the foregoing, the Court concludes participation in the Program, and manufacturer's participation in Medicare and Medicaid generally, is voluntary, even if manufacturers, like those represented by PhRMA, have a considerable economic incentive to participate. See Livingston Care Ctr., Inc. v. U.S., 934 F.2d 719, 720 (6th Cir. 1991) ("[P]articipation in the Medicare program is a voluntary undertaking."); Baptist Hosp. East v. Sec'y of HHS, 802 F.2d 860, 869 (6th Cir. 1986) ("[P]articipation in the Medicare program is wholly voluntary.

If any provider fears that its participation will drive it to insolvency, it may withdraw from participation.").

The Fifth Amendment does not prevent the federal government from placing conditions on a manufacturer's voluntary participation in Medicare programs. See Boehringer Ingelheim, 2024 WL 3292657. The Court concludes that because Plaintiffs' participation in the Program is voluntary, Plaintiffs do not have a protected property interest to sell drugs to Medicare at their professed "fair market value" nor do they have a property interest in their expectation that they will continue selling their drugs to Medicare at a fair market value. See Novo Nordick, 2024 WL 3594413, at *6.

iii. Patients' Interest

Plaintiffs briefly submit that patients, such as those served by NICA members and those represented by GCCA, have property interests in ensuring existing products remain available to Medicare and Medicaid beneficiaries and in the availability of future products brought to market for *any* patients. (Dkt. # 60 at 36.) According to Plaintiffs, HHS's "drug-selection decision may be one of life and death." (Id.)

The Government responds that Plaintiffs cite no authority for the proposition that patients have a constitutional right to have all current Medicare and Medicaid products remain available through those programs forever. (Dkt.

70 at 54.) The Court agrees that Plaintiffs' proposed interest on behalf of patients is far too attenuated to establish a cognizable property interest. See Midtown Hosp. v. Miller, 36 F. Supp. 2d 1360, 1365 (N.D. Ga. 1997) ("Courts have regularly held that a citizen has no liberty interest in obtaining a particular medical procedure or a particular drug."); cf. Shah v. Azar, 920 F.3d 987, 996 (5th Cir. 2019) (concluding healthcare physicians and providers do not have a property interest in being a provider in federal health care programs).

In sum, Plaintiffs cannot demonstrate that the Program deprives them of a protected interest and therefore their Due Process Clause claim fails as a matter of law. The Government is entitled to summary judgment on this claim.

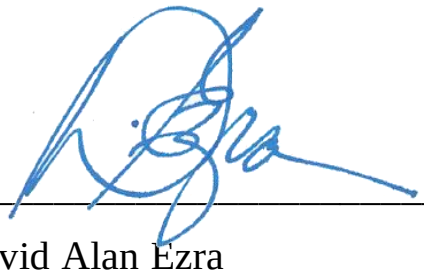
CONCLUSION

Based on the foregoing, the Court (1) **DENIES** Plaintiffs' Motion for Summary Judgment (Dkt. # 60), and (2) **GRANTS** Defendant's Cross-Motion for Summary Judgment. (Dkt. # 70.)

Because the Government is entitled to summary judgment on Plaintiffs' constitutional claims, they are **DISMISSED WITH PREJUDICE**. The Clerk's Office is **INSTRUCTED TO ENTER JUDGMENT and CLOSE THE CASE.**

IT IS SO ORDERED.

DATED: Austin, Texas, August 7, 2025.



David Alan Ezra
Senior United States District Judge